PATENT COOPERATION TREATY

19/4-05

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
Ström & Gulliksson IP AB
Lindholmspiren 5
417 56 Göteborg

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	07-10-2004
Applicant's or agent's file reference P16776PC/MH	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/SE 2004/000998	21.06.2004	19.06.2003

International Patent Classification (IPC) or both national classification and IPC
A61B 5/103, A61B 10/00, A61C 19/04, A61F 2/02

Applicant
INTEGRATION DIAGNOSTICS LTD et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further opinions, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/SE
Patent- och registreringsverket
Box 5055
S-102 42 STOCKHOLM
Facsimile No. +46 8 667 72 88

Authorized officer
Anna Malmberg /OGU
Telephone No. +46 8 782 25 00

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/SE 2004/000998

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/SE 2004/000998

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1-15

because:

☒ the said international application, or the said claims Nos. 1-15 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

Claims 1-15 relate to a method of treatment of the human body by surgery or by therapy/ a diagnostic method practised on the human or animal body/Rule 67.1(iv).

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/SE 2004/000998

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	16-29	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	16-29	NO
Industrial applicability (IA)	Claims	16-29	YES
	Claims		NO

2. Citations and explanations:

Prior art

Reference is made to the following documents:

D1: US 2002/0143268 A1
D2: WO 03011133 A1

Document D1 discloses a medical implant testing system consisting of a transducer assembly (10,20,80,30) and an apparatus (100,200) for detecting the stability of a bone implant. The transducer assembly, which is detachable from the apparatus, consists of a member adapted to be releasably attached to the implant, which member consist of an exciter transducer (50) and a receiver transducer (60). The exciter transducer generates oscillations in the member and the receiver transducer receives the measured resonance frequency of the member. In an alternative embodiment, a single transducer element can be used both as a vibration exciter and a signal receiver. The measured signals are sent via the cable (20) to the apparatus, where the signals are processed and analyzed. (See the whole document but especially the abstract, paragraphs [0008] - [0011], [0042] -[0050],[0057]-[0058] and figures 1,2 and 4A.)

Document D2 discloses a medical implant system including arrangement for testing the physical states of the implant (1) in the environment thereof. The arrangement comprises a member (7) attached to the implant, which member comprises a detectable part (8), and detecting means (9) for contactless detection or for example oscillations of the implant. The detecting means (9) detects electromagnetic signals from the detectable part (8), which signals are

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box V.

sent to a measuring apparatus (11). The detectable part may consist of an optical element and the detecting means may detect the reflected optical signal. (See the whole document but especially page 11, line 15-25, page 12, line 7-24, page 16, line 9-11 and figure 1.)

Statement of reason

The invention according to claims 16-28 discloses an arrangement for testing an implant, which arrangement discloses a member detachably attached to an implant. It is important to ensure, in a non-destructive and clinical way, that implants are correctly implanted and that the quality of the union between the implant surface and the bone is satisfactory. The inventive concept is that oscillations are generated in the member and a detecting means which contactlessly detects the electromagnetic resonance frequency of the member. The oscillations can also be of optical nature. The measured resonance frequency is processed an analyzed.

What is mentioned in D1 is considered to represent the closest prior art.

The invention according to claim 16 differs from what is mentioned in D1 only in that the measurement of the resonance frequency according to invention is wireless. This difference gives an alternative way to measure the resonance frequency of the member attached to the implant.

There is a problem of how to arrange a detachable transducer measuring device to measure the quality of the union between the implant and the bone in an efficient way without destroying the implant or anything else in the oral cavity.

A person skilled in the art facing this problem would find a solution in D2. It is stated in D2 that detection of vibrations, or other characteristics such as reflected optical light, can be made wirelessly. Also, it is stated in D1 that the transducers are detachably connected to the circuitry for driving the vibrations and detecting the response. It is considered as obvious to a person skilled

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box V.

in the art, when arranging a detachable transducer assembly, to arrange the transducers detachably from the member and drive the vibrations and detect the resonance frequency wirelessly with electromagnetic or optical energy.

A person skilled in the art, having the arrangement from D1 as a starting point, aiming to solve the identified problem would with knowledge of D2 arrange the transducer assembly separate from the member so that the driving of vibrations and the detection of the responding resonance frequency is made wirelessly.

Since D1 and D2 both relate to the same technical field and no unexpected effect is obtained the combination of what is known from D1 and D2 is considered obvious to a person skilled in the art. The invention according to claim 16 is thus not considered to involve an inventive step.

What is mentioned in claims 17-20 and 24-28 are considered as obvious details to a person skilled in the art. Therefore the invention according to claims 17-21 and 24-28 lacks an inventive step.

What is mentioned in claims 21-23 deals with detecting the resonance frequency of the member by optical means. To measure resonance frequency of a vibrating member by optical means is known from D2. Therefore, the invention according to claims 21-23 lacks an inventive step.

What is mentioned in claim 29 is not a part of the inventive concept and solves another problem namely the problem to prevent spreading of viruses and diseases. The use of disposable articles in medical situations is considered as a general standard within the medical area and therefore the invention according to claim 29 lacks an inventive step.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/SE 2004/000998

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawing or on the question whether the claim are fully supported by the description, are made:

The invention is not clearly defined in claim 1 in regard that the field wherein the method is supposed to be performed is not clear. According to the description the method is supposed to be performed within the area of medical implants. No other field of applications is mentioned. Therefore, claims 1-15 has been searched in part and the search has been executed within the area of medical implants. However, since the claims 1-15 refers to method of treatment of the human body by surgery or by therapy/ a diagnostic method practised on the human or animal body/Rule 67.1(iv), no opinion has been based on these claims. The independent claims 16 and 29 clearly refers to the area of medical implants and the opinion has been based on the prior art found in that area.